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10/657,354	09/08/2003	Joanna Graft	480062002500	1649

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MORRISON & FOERSTER, LLP  
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LOS ANGELES, CA 90013-1024

EXAMINER
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CARPENTER, WILLIAM R

ART UNIT	PAPER NUMBER
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3709

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09/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/657,354

Applicant(s)

GRAFT ET AL.

Examiner

William Carpenter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/08/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. As regards to Claim 3, Claim 3 references a tension created "between said first and second openings and the respective tip section inserted therethrough". The Abstract appears to provide the basis for this claim stating that the device "may be configured to provide a tension to prevent relative movement of the tip section(s) with respect to the dividing element" and no further clarification appears to be present in the specification. However, it is unclear as to whether this tension is created between the two openings, the individual openings and the inserted distal tip, or between the distal tips themselves.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5, 8, 10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 7,077,597 ("Davies").

As regards to Claim 1, Davies teaches a device comprising a body (Figure 1, Item 1) having a proximal end (Figure 1, the end at the bottom of the page) and a distal end (Figure 1, the end at the top of the page). The body comprises a first opening (Figure 1, Item 5) and a second opening (Figure 1, Items 2, 3, or 4) spaced apart by a distance sufficient to ensure the separation of the two distal tip sections of a split-tip catheter. While Davies does not teach his device in use with a split-tip catheter the mention of a split-tip catheter is only an intended use, not a positive limitation. All that is required is that the device of Davies has the ability to function as a split tip catheter divider. Clearly, the device of Davies is capable of functioning as such as a result of the structural similarities to the device claimed by Applicant.

As regards to Claim 2, Davies does not explicitly indicate the distance between the first and second openings. However, we are able to reasonably infer the distance based on the geometry of a standard three-ring binder. Given the size of a three ring binder and the use of either 13 or 14 inch long legal paper (Column 1, Lines 25-27) the distance between the first and second opening could be as long as approximately 11 inches (Figure 1, the distance between openings 5 and 2) or as short as approximately 2 inches (Figure 1, the distance between openings 5 and 4). These values are derived using a standard spacing of 4.5 inches between the rings of the binder and a spacing of

1 inch between the edge of the page and the 1<sup>st</sup> and 3<sup>rd</sup> rings. Page 6, Lines 5-7 of Applicant's disclosure states that one embodiment of the device would have spacing between the two openings of "approximately 2 inches" which would be capable of accommodating both "14.5 Fr and 16 Fr catheters". This distance of approximately 2 inches is assumed to be in compliance with the limitations set forth by Claim 2. As such, the distance of the device of Davies satisfies the limitations by teaching a distance between openings of approximately 2 inches or greater.

As regards to Claim 3, while it was unclear as to what tension was created by the disclosed dividing element, due to structural similarities with Davies it was assumed that Davies too would create the same tension as recited in Claim 3. The invention as disclosed by Applicant comprises two openings in a thin sheet of material, spaced apart by a disclosed distance of approximately two inches. (Page 6, Lines 5-7) The device of Davies also consists of two openings in a thin sheet of material, spaced apart by a distance of approximately 2-3 inches based on the geometry of the standards sized three-ring binder (See above rejection of Claim 2). Given these virtually identical configurations it follows that the device of Davies would create the same tensions between the same elements as the disclosed invention of Applicant.

The following is a recitation of MPEP § 2112 –

[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on '*prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

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Once a prima facie case of inherency has been established the burden shifts to Applicant to show that the patentable feature as claimed is not an inherent characteristic of the prior art.

As regards to Claim 4, Davies teaches a device that is configured for attachment to a packaging tray. Davies teaches a circular aperture at the distal end (Figure 1, Item 2) that is designed specifically for the purpose of attachment, in the instant case a binding ring of a standard three-hole binder (Figure 2, Item 8). The mention of a packaging tray is not a positive limitation, rather only a configuration for attachment is required. As such, the limitations of Claim 4 are met by Davies.

As regards to Claim 5, Davies teaches the distance between the first opening (Figure 1, Item 5) and the proximal end (Figure 1, the end at the bottom of the page) to be less than the distance between the second opening (Figure 1, Item 3 or 4) and the distal end (Figure 1, the end at the top of the page).

As regards to Claim 8, Davies teaches his device to be 13 or 14 inches from the proximal end to the distal end (Column 1, Lines 25-27).

As regards to Claim 10, Davies teaches his device to incorporate a weakened section between the first and second holes (Figure 1, Item 7). In the instant case, the weakened area is represented by a fold line, which allows legal size paper to be folded such that it will fit in a standards letter sized three-ring binder.

As regards to Claim 11, Davies teaches his device to incorporate a weakened area between the first opening and an edge of the body (Figure 3g, Item 23). In the

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instant case this weakened area is represented by a perforated slit that allows the paper to be unfolded without opening the binder rings.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent No. 7,077,597 ("Davies") as applied to Claim 1 above, and further in view of WO 03/029020 A1 ("Jung").

As regards to Claims 6 and 7, Davies teaches the limitations of Claim 1, on which Claims 6 and 7 are dependent. What Davies fails to teach is that the first and second openings comprise slits. However, Jung teaches paper and a method for binding it that uses x-shaped slits (Figure 2, Item 21a) as a variant of traditional circular apertures (Figure 3, Item 21b). Jung teaches these variants in the same context of the openings in

Davies, binding leaves of paper into an attachment device. It would be obvious to one having ordinary skill in the art to substitute x-shaped slits for the circular apertures of Davies, as these two types of openings are interchangeable as suggested by Jung

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 7,077,597 ("Davies") as applied to Claim 1 above, and further in view of US Patent No. 5,047,121 ("Kochar").

As regards to Claim 9, Davies teaches the limitations of Claim 1, on which Claim 9 is dependent. What Davies fails to teach is his device to be composed of polyethylene. However, Kochar teaches a synthetic pulp paper product composed of polyethylene (Abstract, Lines 1-4). Polyethylene paper is used as an alternative to wood pulp paper, especially concerning important documents where resistance to degradation and water damage is desired. The device of Davies is used specifically with legal documents, such as contracts (Column 1, Lines 25-27). It would have been obvious for one having ordinary skill in the art to print the legal documents of Davies on a high-grade polyethylene paper as disclosed by Kochar as to prevent against damage and degradation.

20. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,382,568 ("Snell") in view of US Patent No. 4,925,452 ("Melinyshyn et al.").

As regards to Claim 12, Snell teaches a dividing element for use with medical devices and instruments, particularly tubular devices, order to keep individual leads separate (Abstract). This dividing element has a body (Figure 1, Items 12 and 16 in combination), a proximal end (Figure 1, the face generally pointed to by Arrow 12) and a



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distal end (Figure 1, the face directly opposite the proximal end). Snell further teaches a 1<sup>st</sup> and 2<sup>nd</sup> opening (Figure 1, Items 12a and 12b) spaced apart by a sufficient distance to ensure the separation of two tip sections. What Snell fails to teach is this device specifically for use with split-tip catheters. Melinsyhyn et al. provides the specific motivation as to why such a device would be useful with respect to split-tip catheters. Melinsyhyn teaches the importance of limiting relative movement of the lumen of a split-tip catheter, specifically during storage, to prevent damage to the catheter lumen. (Column 2, Lines 56-61). While Melinsyhyn targets this concerning by fusing the two lumen with a weakened membrane, one in the art would reasonably recognize and appreciate the device of Snell would function equivalently, to the device as taught by Melinsyhyn, preventing relative movement of the distal lead of a split-tip catheter. For this reason, it would have been obvious for one having ordinary skill in the art to insert the distal tips of a split-tip catheter in the openings of Snell as to prevent relative movement.

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Carpenter whose telephone number is (571) 270-3637. The examiner can normally be reached on Monday through Thursday from 7:30AM-5:00PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

WC  
08/22/2007



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**SUPERVISORY PATENT EXAMINER**